UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **Hon. Renée Marie Bumb** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

TPP BELLWETHER TRIAL PLAINTIFFS' MOTION FOR LEAVE TO REOPEN EXPERT RECORD FOR LIMITED PURPOSE OF ADDRESSING INTERVENING CHANGE IN LAW

I. INTRODUCTION

TPP Bellwether Trial Plaintiffs respectfully move to reopen the expert record in the TPP Subclass Bellwether Trial Case for the limited purpose of allowing the parties to supplement in light of the intervening change in the law of the case as to TPP Trial Plaintiffs' breach of warranty claims.

On April 7, 2025, this Court ruled TPP Plaintiffs cannot rely on Dr. Conti's opinion that the VCDs were economically worthless because the jury must weigh the non-economic, scientific evidence about the "risks and dangers [of NDMA] against the evidence of the benefits conferred to determine the value of the VCDs

received." *See* ECF 3018 at 20-21.

At the April 28, 2025 CMC, the Court agreed that the upshot of its April 7 ruling is that TPP Plaintiffs should have an economic "translating mechanism" to help the jury evaluate the economic impact associated with the scientific or general causation evidence about NDMA (e.g., scientific and medical expert testimony about the risks associated with NDMA, etc.) on the value of the VCDs purchased. *See* 4/28/25 Tr. at 40-41. In other words, if the jury finds based on the scientific evidence presented that the risks were *X*, that 'translates' to a *Y*% reduction in value: the amounts paid minus the discount (*Y*%) for the risks equals awardable damages. The discount could be up to 100% (i.e., full refund damages) if supported by the evidence. *See, e.g.*, ECF 3018 at 18 ("[t]o be clear, a full refund may be awarded in certain cases"); at 25 (reasoning that "[a] jury may very well find that a full refund is appropriate" in this case).

The Court's April 7, 2025 ruling was the first time in this case that the Court determined that the law of breach of warranty damages *requires* a jury to consider the scientific general causation evidence of risk as against the clinical benefit that may have been conferred and, in turn, translate that into economic loss in a benefit of the bargain analysis. Prior to this, the law of the case—up until both since-

adjourned trial dates— was that the jury did *not* need to consider such evidence,[1] and then in July and September 2024 this Court's view began to evolve.

The April 7, 2025 decision went further, and is the first time that the Court **ordered** that breach of warranty law requires presentation of scientific or 'general causation' type evidence and consideration of clinical benefit conferred against such risk in order to establish the economic impact to the drugs' value or worth – as opposed to simply allowing Defendants to make this argument as against Plaintiffs' arguments for diminished or absent value based primarily on the applicable regulatory law. Prior to this order, neither side was required to submit an expert report "translating" the scientifically-grounded risks into economic impact for damages purposes. That is now required and Plaintiffs seek leave to retain and utilize an expert(s) to address that new requirement.

The Parties argued this point to the Court at the April 28 CMC, and the Court

[1] *See, e.g.*, ECF 2694 at 65 n.61 (03/26/24) ("there seems a small, if any need, need for inquiry into individual facts of consumers' ingestion of VCDs . . . Ps seek to present evidence to the fact-finder as to what the defendants should have done to prevent or discover the contamination. And as an answer to that question, individualized facts about individual consumers' causation liability are of little direct relevance."); ECF 775 at 20 (01/22/21) ("**This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for**.") (emphasis added).

ruled that it was reasonable to permit the Plaintiffs to retain a new economic expert(s) to address this issue:

> "Get your experts ready, get your economists ready. There's got to be a translating factor. If you folks can't work it out, you'll work it out with Judge Vanaskie. I'm going to – I am not going to try a TPP trial until I'm satisfied that there is a connecting piece….Just go get it done."

See 4/28/25 CMC Tr. at 43-44.

Defense counsel then argued to the Court that this would require the parties to re-open discovery, and seemingly persuaded the Court to reverse its determination that Plaintiffs could retain a new economic expert(s). *See* 4/28/25 CMC Tr. at 44, 47. However, defense counsel's argument was incorrect, and is a red herring. Plaintiffs are not seeking to re-open discovery (which would be a misnomer anyway since in this MDL the exchange of necessary documents and information continues, and will continue until the litigation is concluded, as a matter of course as with any MDL). Plaintiffs are simply seeking to utilize the *existing* record with a new expert to address the translating mechanism embraced by the Court at the April 28, 2025 CMC. Defendants can then respond to that new expert(s) and the Court can then evaluate the opinions in the ordinary course.

As initially found by the Court, good causes exists to grant this motion. For one, this Court already directed the parties to proceed in this fashion but was persuaded to reverse course based on Defendants' incorrect suggestion that this would trigger a wholesale re-opening of discovery.

Moreover, denial would be significantly prejudicial to TPP Plaintiffs. There is little if any prejudice to Defendants, given that they labored under the same prior law of the case as Plaintiffs,[2] and they would have an opportunity to depose Plaintiffs' expert(s) and submit their own supplemental report(s).

There will be no disruption to the trial schedule because a new trial date has not been set. In the interim, the Court has set a trial schedule for waves of personal injury bellwether cases, where the Court will have the opportunity to hear the general causation testimony that is at the center of this issue. On the other hand, unquestionably, the evidence is now extremely important given this Court's legal rulings and significant efficiencies will be gained by allowing this relief.[3]

For the reasons set forth herein, it is respectfully requested that the Court allow the TPP Trial Plaintiffs and Defendants leave to obtain supplemental economic expert reports regarding damages, as the Court initially indicated at the April 28

[2] *See, e.g.*, ECF 3018 at 48 ("Thus far, the parties have been laboring under the assumption that causation was not part of the TPP Trial. But going forward it will be.").

[3] Conversely, as this Court specifically ruled, its opinion only concerns the "TPP Trial" and does not apply to the economic loss consumers and the remaining TPPs, s*ee* ECF 3018 at 2, which are on a different schedule and have not submitted merits or damages expert reports, it would be inefficient to try one class case in the MDL in one manner, and the remaining cases in another manner, where outcomes may differ and with the former trial providing little precedential value to guide the parties in ultimate resolution of the cases in the MDL. Certain TPPs' claims should not be treated differently than others simply because for case management purposes, their trial was set prior to this Court's ruling.

CMC.

II. PERTINENT PROCEDURAL BACKGROUND

Plaintiffs previously set forth in detail the rulings constituting the pertinent law of this case and Plaintiffs' good-faith reliance thereon. *See* ECF 2921. For succinctness, Plaintiffs incorporate that recitation here, and only provide the following high-level, truncated summary:

- At the outset of the litigation, the Court established the legal principle for Plaintiffs' claims that scientific or 'general causation' evidence was not pertinent: "contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless of whether the sold VCDs actually achieved the medical purpose of lowering blood pressure" and that "contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for."[4]

- This legal principle was re-affirmed by the Court early in 2023 at class certification.[5]

- This legal principle was re-affirmed by the Court shortly before the

[4] ECF 775 at 16. Years later, the Third Circuit validated this characterization of the law in *Huertas v. Bayer US LLC*, 120 F.4th 1169, 1178 & n.14 (3d Cir. 2024) ("Indeed, whether through a legal prohibition or a product recall, the end result is the same: if their products are contaminated, they are unusable."); *id.* at 1178 ("Given that contaminated products are unfit for their intended use, they are inherently worth less than the uncontaminated products Plaintiffs thought they were purchasing.").

[5] ECF 2261 at 88 ("The Court has considered carefully all of the parties' arguments and concludes that Dr. Conti has set forth a general calculus, i.e. mathematical model, which, although possibly flawed because the data are not available or forthcoming, **may reliably support her presumption of the worthlessness of the sold VCDs.**") (emphasis added).

first since-adjourned trial date in March 2024, in denying Defendants' motion to decertify the class.[6]

- This legal principle was re-affirmed by the Court in its summary judgment rulings in the TPP Bellwether Case immediately after the March 2024 trial was adjourned.[7]

At the initial hearing on the TPP trial motions conducted by this Court in July 2024, the Court initially indicated that it agreed with Plaintiffs that general causation evidence should not be admissible, *see, e.g.*, 7/23/24 Tr. at 30:5-24 ("I'm not going to keep you all waiting. I think the plaintiffs probably are right [that general causation should be out of the TPP case]."), and that it would be difficult if not impossible for Defendants to establish any value, *id.* at 203:20-22 ("How does it have any value when it's been recalled and you can't sell it?"). The Court then posited that "[i]t's a jury question whether or not the drug had value pre-recall." *Id.* at 205:14-15. The discussion progressed, and illustrates the evolution of the issues, with the Court ultimately indicating at the time that the issue is the level of risk, or whether the contamination presented an "unacceptable risk. Not whether it causes [cancer] or not." *See id.* at 200:17-216:13. The Court's views continued to evolve

[6] ECF 2657 at 7-8 & n.5 ("Ps theory of damages rests **not on a 'biological' basis but on an 'economics' one,** that the supply curve of contaminated drugs the FDA never would have allowed for sale is zero, making the drugs unmerchantable. Contrary to Ds characterization, Ps theory of damages, while not biologically based, is nonetheless based in recognized caselaw as economic theory … Accordingly, the Court finds no legal support for decertifying the TPP subclasses by attacking Conti's model of damages") (emphasis added).

[7] ECF 2694 at 20 & n.17, 56.

through the Fall of 2024.

The Court's April 7 decision changed the law of the case in a number of significant ways:

- This Court ruled that adulterated and contaminated prescription drugs are not necessarily economically worthless, *see contra, e.g.*, ECF 775 at 16. (01/22/21).

- This Court determined that "therapeutic value" is relevant to assigning economic value to the VCDs, *see contra, e.g.*, *id.*

- This Court decided that VCDs consumed prior to disclosure of contamination might not be worthless, *see contra, e.g.*, *id.*

- This Court stated that scientific or 'general causation' type evidence **must** be presented to a jury,[8] *see contra, e.g.*, ECF 2694 at 65 n.61 (03/26/24).

- This Court concluded the VCDs were lawfully sold because they were sold without knowledge of the contamination, *see contra, e.g.*, ECF 2581 at 17 (01/05/24).[9]

- This Court viewed the *BCBS* case[10] as factually distinguishable because the Court found the FDA allowed the adulterated medications to be sold and bought by TPPs despite knowledge of the adulteration, even though the *BCBS* plaintiffs sought damages for drugs sold between 2002-2005, and the FDA did not declare adulteration until 2005, *see contra, e.g.*, ECF 2694 at 61; ECF 2261 at 60-61.

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[8] *See* 4/28/25 Tr. at 19-20.

[9] ECF 2581 at 17 (excluding in part defense expert Dr. Williams: "Williams states that the contaminated VCDs could not have been 'adulterated' before the FDA became aware of the contamination in the summer of 2018. This is sophistry, which attempts to avoid a retrospective characterization of Teva's finished dose products as 'adulterated' from the start of the nitrosamine contamination.").

[10] *BCBS v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 538, 543-44, 554 (E.D. Pa. 2019).

- This Court found that unlike *Huertas*, where consumers were directed to stop using the purchased product, the VCDs were consumed and functioning as expected. However, here, similar to *Huertas,* the FDA instructed consumers to return their "unused medication" to the pharmacist once the new medication is prescribed. https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan.

- This Court found aspects of Dr. Conti's economic worthlessness opinion was *ipse dixit*, *see contra, e.g.*, ECF 2261 at 88-89 (02/08/23).[11]

In sum, the parties proceeded for years under rulings establishing that scientific or 'general causation' type evidence on the VCDs' risks was not likely pertinent in the TPP Bellwether Case to determine the benefit of any lost bargain. The parties proceeded for years under rulings establishing that the VCDs at issue may well have been adulterated and unlawfully sold regardless of anyone's knowledge of the NDMA and/or NDEA contamination. Given same, there was no need or pathway for the parties to present economic evidence to 'translate' those risks for damages calculation purposes. And in turn, the TPP Plaintiffs built their case around establishing the adulteration of the VCDs at the time they were sold, which the Court had previously determined was the "central issue" in the entire litigation. ECF 2694, at 32 ("Ultimately, then, whether ZHP[']s API was adulterated is **the central fact** in dispute in this matter, not only for the breach of warranty claim

[11] ECF 2261 at 88-89 (finding Dr. Conti's opinions had "sufficient scientifically reliable underpinnings").

but for violation of state consumer protection laws and fraud. If the API is found to be statutorily adulterated, then the finished dose products were necessarily adulterated." (emphasis in original); *see also* id. at 58 (ruling that TPPs' presentation of case that "the VCDs are worthless [] hinge[s] on the very central question of the VCDs adulteration and raise[s] a genuine dispute of material fact for the factfinder").

Plaintiffs recognize that this Court's recent ruling as to damages has changed the legal landscape of this case.[12] It is now established that scientific or 'general causation' type evidence *is* required in the TPP Bellwether case; the risks and benefits can and should be considered by the jury; that the scientific evidence can then be 'translated' by economic analysis for the jury's assessment of damages; and that TPP Bellwether Plaintiffs' complaint reasonably encompasses the foregoing theory.[13]

III. LAW AND ARGUMENT

Courts in this Circuit view a request to supplement the expert record under the good cause standard under Federal Rule of Civil Procedure 16. *See, e.g.*, *Morgan v. Gandalf, Ltd.*, 165 Fed. App'x 425, 430-31 (3d Cir. Jan. 31, 2006). As a failure to

[12] TPPs and Plaintiffs reserve all rights regarding appellate review of the Conti Opinion.

[13] Indeed, the Court, the parties and the law all agree that the correct measure of damages for a breach of express warranty claim is "the difference in value between what was bargained for and what was received," known as the benefit of the bargain theory. ECF 3018 at 9. And, that the question of damages is for the jury to decide. ECF 3018 at 10.

allow supplementation is tantamount to exclusion of expert evidence, courts in this Circuit also typically consider the factors set forth in *Meyers v. Pennypack Woods Home Ownership Association*, 559 F.2d 894, 905 (3d Cir. 1977) when resolving a motion such as this one. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 298 (3d Cir. 2012). Those factors are:

> (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence.

ZF Meritor, 696 F.3d at 298 (internal quotation marks and citation omitted). "The importance of the evidence is often the most significant factor." *Id.*

Good cause supports TPP Trial Plaintiffs' request here, as do the *Pennypack* factors. TPP Trial Plaintiffs labored under the law of the case discussed *supra* Part II on breach of warranty damages for years, and mustered their expert evidence based on same.

This Court has now ruled that such evidence is not only admissible but necessary, and further that such evidence should be further translated by an economic expert to assist the jury to determine potential breach-of-warranty

damages.[14] Plaintiffs accept this for purposes of moving forward on behalf of the thousands of certified class members,[15] and are eager to present to a jury Plaintiffs' considerable evidence, meticulously and costly obtained over the years, about the VCDs' risks. But to say these class-wide breach of warranty claims for a subset of the classes certified in the MDL now fail because of a new shift in how damages – not liability – must be presented to a jury would be unfairly prejudicial to Plaintiffs, who simply ask for leave to present an expert or experts who can address the issue that the Court identified in its April 7, 2025 opinion. *See, e.g.*, *Home Depot USA, Inc. v. LaFarge N. Am, Inc.*, 59 F. 4th 55, 64, 66 (3d Cir. 2023) (transferee courts should manage MDLs "to promote efficiency **and avoid unfairness** . . . That said, efficiency must not be achieved at the expense of preventing meritorious claims from going forward") (emphasis added) (internal quotation marks and citations omitted).

Courts find good cause exists to reopen expert discovery when the law of the case changes in the same or similar manner as here. For example, in *Anthem, Inc. v. Express Scripts, Inc.*, 660 F. Supp. 3d 169, 185 (S.D.N.Y. 2023), the court allowed a TPP plaintiff to supplement the expert record where that court reached a different conclusion of law about the scope of contract damages than it had before, and after the parties had already tendered expert reports. In *Rimbert v. Eli Lilly & Co.*, 647

[14] No "translation" is required in the event a jury finds, consistent with a fundamental defect that the VCDs were rendered worthless.
[15] Plaintiffs expressly preserve all of their appellate and related rights.

F.3 1247, 1256 (10th Cir. 2011), the Tenth Circuit found an abuse of discretion where successor judge did not allow submission of new expert reports after successor judge revisited predecessor judge's *Daubert* rulings. *See also Colvin v. Keen,* 900 F.3d 63, 69 (2d Cir. 2018) (explaining that a district court abuses its discretion under the law of the case doctrine when it makes "a change of ruling" that "cause[s] prejudice to the appellant"). Other courts have allowed reopening of expert discovery in similar circumstances as well.[16]

Moreover, TPP Bellwether Plaintiffs have acted diligently and in good faith by bringing this motion promptly after the April 28 CMC. *See, e.g.*, *Shire Labs., Inc. v. Nostrum Pharms. Inc.*, No. 03-4436, 2005 WL 8176149, at *4 (D.N.J. Oct. 7, 2005).

There is no countervailing prejudice to Defendants. There is no trial date for the TPP Bellwether Trial. The parties will be trying a series of personal injury

[16] *See, e.g.*, *Kimmel v. Mass. Bay Ins. Co.*, No. 21-12743, 2023 WL 8714336, at *14 (D.N.J. Dec. 13, 2023) (granting plaintiff leave to file second affirmative expert report); *Kewazinga Corp. v. Microsoft Corp.*, No. 18-cv-4500, 2022 WL 4236301, at *5 (S.D.N.Y. Sept. 14, 2022) (inviting argument on request to file supplemental expert reports); *Alta Wind I Owner Lessor C v. U.S.*, 154 Fed. Cl. 204 (Fed. Cl. 2021) (successor judge permitted plaintiff to submit new expert reports after change in law on how predecessor judge had directed calculation of damages); *Via Vadis, LLC v. Amazon.com*, No. 14-cv-0813, 2022 WL 1667560, at *1 (W.D. Tex. May 24, 2022) (allowing expert supplementation); *Generations at Pinnacle Peak LLC v. Whitestone Pinnacle of Scottsdale-Phase II*, No. CV-17-4597, 2021 WL 9597885, at *8 (D. Ariz. Feb. 22, 2021) (refusing to strike new expert reports submitted after court struck original damages report for lack of separate expert report on which damages were to be based).

bellwether cases in the near term, and any work on supplemental economic loss expert evidence now for the TPP Bellwether Trial will be usable in the other class cases (in which merits and damages expert reports are not yet due).

The *lack* of genuine prejudice is even more pronounced under these circumstances in an MDL. For instance, in the *Zoloft* MDL, Judge Rufe dealt with a similar issue in which the plaintiffs sought to submit a new expert's report after she excluded other plaintiff experts' opinions. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, No. 12-md-2342, 2015 WL 115486 (E.D. Pa. Jan. 7, 2015). The defendants objected, arguing it would result in additional expense to litigate the admissibility of the new expert's testimony. Judge Rufe disagreed, finding that this type of purported "prejudice is not of a character sufficient to warrant denial of the motion." *Id.* at *2. She also noted there was "every possibility" the new expert likely would be presented in other currently pending or to-be-filed cases in the MDL, and it was more efficient to address the new expert's opinions now. *Id.*

Moreover, as expert evidence can be of "critical importance," *In re Zoloft*, 2015 WL 115486, at *2, and exclusion could mean a plaintiff cannot pursue damages even if they win on liability, the "preferred means" of dealing with a party's attempts to offer new evidence is a continuance as opposed to exclusion. *See ZF Meritor*, 696 F.3d at 297, 299 (quoting and citing *EEOC v. General Dynamics Corp.*, 999 F.2d 113, 116 (5th Cir. 1993)); *see also Coleman v. W. Bend Mutual Ins. Co.*, No. 21-cv-

180, 2022 WL 18530886, at *7 (N.D. Ind. Dec. 13, 2022) (allowing new expert report; "the law prefers that cases be resolved on their merits, not technicalities") (internal quotation marks and citation omitted); *White v. Beaver Cty.*, No. 17-998, 2019 WL 5395212, at *2 (W.D. Pa. Oct. 22, 2019) (collecting cases for proposition that Third Circuit regularly finds the disruption of trial *Pennypack* factor does not support exclusion of expert report "if no trial date has yet been set").[17]

IV. CONCLUSION

The TPP Bellwether Trial was within days of trial twice, in March 2024 and November 2024. The Court's April 7, 2025 decision was the first time in this MDL that the Court stated that scientific or 'general causation' type evidence must be part of that trial as part of a jury's valuation, weighing such risks against perceived clinical benefits and only then determine "value" in a benefit of the bargain damages analysis.

The Court will hear the general causation evidence at the upcoming personal injury bellwether trials. And there will still be both a TPP and other class economic loss trials premised on the contamination of these VCDs, with merits and expert reports not yet due. The parties now need to do what the Court said at the April 28

[17] Moreover, this MDL's scheduling deadlines have been modified before, including most recently to allow TPP Trial Defendants to file another summary judgment motion over a year after the original deadline for such motions, without Defendants articulating the particular grounds on which they seek a redo or demonstrating good cause. *See Drippe v. Tobelinski*, 604 F.3d 778, 84-85 (3d Cir. 2010).

conference: "Get your experts ready, get your economists ready. There's got to be a translating factor. If you folks can't work it out, you'll work it out with Judge Vanaskie . . . Just go get it done." 4/28/25 CMC Tr. at 43-44. Plaintiffs are ready to do just that. It is respectfully requested that the Court grant this motion and order the parties to work out the schedule contemplated at the April 28 CMC, and submit any disagreements about same to Special Master Vanaskie.

Dated: May 14, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May 2025, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ David J. Stanoch
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